RetCam Shuttle

Wide-Field Imaging System

Service Manual

PN 20-000107 Rev. A

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Clarity
medical systems

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1.0 Notices and Labels

Rated for Continuous Operation

IEC 60601-1:1995

Accessories equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC6950 for data processing equipment and IEC 60601-1-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible to ensure the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical services department or your local representative.

WARNING: This equipment should be connected using the power cord supplied by Clarity.

WARNING: To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The RetCam Shuttle uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RetCam Shuttle is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the RetCam Shuttle or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The RetCam Shuttle is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RetCam Shuttle requires continued operation during power mains interruptions, it is recommended that the RetCam Shuttle be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	0.15-80 MHz, 3 Vrms, 80% 1 KHz AM	0.15-80 MHz, 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam Shuttle, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	80-2500 MHz, 3/m, 80% 1 KHz AM	3 V/m	

WARNING: Interference may occur in the vicinity of equipment marked with this symbol. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Safety Information

This medical equipment is in compliance with UL60601-1/CAN/CSA C22.2 No.601-M90

This medical equipment is IPX1 labeled and in accordance with IEC 60529.

European Authorized Representative address

EC REP

MediMark® Europe Sarl. 11, rue Emile Zola. BP 2332F-38033 Grenoble Cedex 2. FranceTel: +33 (0)4 76 86 43 22 Fax: +33 (0) 4 76 17 19 82e-mail: info@medimark-europe.com

FDA (USA) Notices

This device is listed with the United States of America (USA) Food and Drug Administration (FDA) for commercial distribution.

Device Trade Name	RetCam Shuttle
Product Code	86 HKI
Classification Name	Ophthalmic Camera
Classification Regulation Number	886.1120
Medical Device Classification	Risk Class II

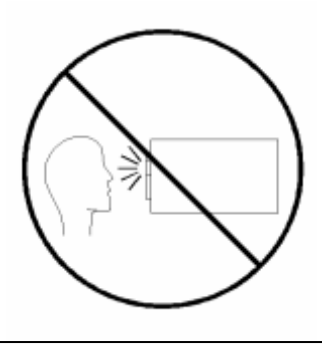
Important User Safety Notices

1. Remove the lens and store it in the lens box and secure the handpiece in its storage compartment inside the cart before moving the cart to a new site.
2. Carefully inspect and clean the lens piece before each use. DO NOT use if the front lens of the lens piece is nicked or scratched.
3. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.
4. Unauthorized modifications or additions to the software or hardware of the system will void the warranty and could adversely affect the system function.
5. DO NOT AUTOCLAVE any part of this device.

6. Do not use the white light source for longer than 5 cumulative minutes on the same eye during an exam.
7. Appropriately power down and unplug the unit and allow the light source bulb to cool before replacing it.

8. Never connect the RetCam Shuttle to a network or any externally powered devices or peripherals *during imaging*.
9. Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.
10. The RetCam Shuttle is for use by or on the order of a health care professional.

Labels / Symbols

	Intensity Decrease
	Intensity Increase
	Focus Closer
	Focus Distant
	Snap Switch
	

Protective earth (ground)

Alternating current (AC)

Type BF Equipment (applied part is handpiece)

Do not use if dropped

Clean lens piece after use

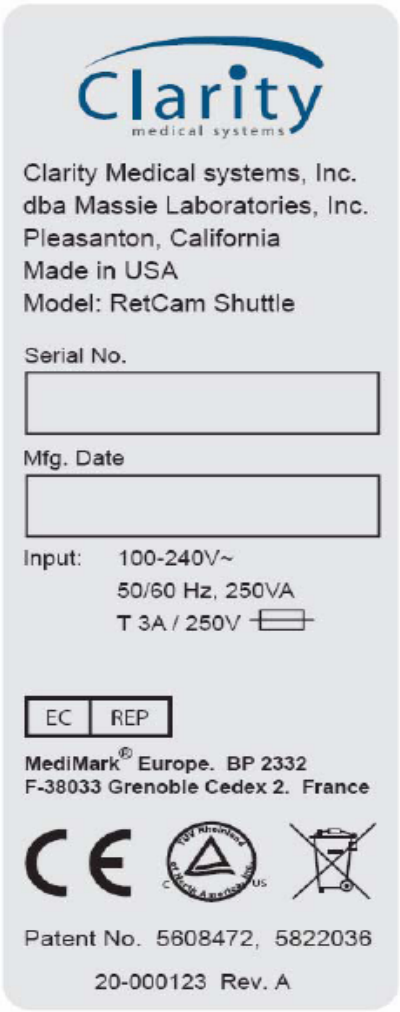
IPX1

Footswitch in accordance with IEC 60529

Separate collection of waste at end-of-life as required by European directives.

Equipment suitable for direct current (DC) only using the indicated terminal. Notebook computer can be powered from this terminal.

Label



For RetCam Shuttle Systems:

Input and Fuse

100-240V~

50/60 Hz, 250VA

T 3A / 250V

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

2.0 Introduction

The RetCam Shuttle from Clarity Medical Systems is an integrated, mobile wide-field imaging system. Clarity designed the RetCam Shuttle to be maneuverable in constrained areas and for total system transport within and between hospitals and clinics. The RetCam Shuttle is made to have site awareness, which means it is made to be aware of the physical location where it is being operated. Thus, it prompts you at start-up to identify the operating location and it identifies saved data according to location. It also offers networkability, to support data transfer to and from the system and the multiple locations where it may be used.
With the exception of a fluorescein angiography light source and attached printers, the RetCam Shuttle offers the same basic functionality as the RetCam II, the leading choice for wide-field pediatric retinal imaging. The imaging system, including camera and lens choices, is identical, as are the image viewing, processing and other utilities.

The system is designed for easy operation by either a clinician or trained staff members. Using the integrated notebook computer, you have point-and-click access to all functions via the system software. You can use the RetCam Shuttle to quickly capture, display, process, and transfer high resolution digital images.

Indications for Use
For general ophthalmic imaging, including retinal, corneal, and external.

CAUTION: Use of this manual is intended for qualified technical personnel only. If in doubt, please contact the manufacturer before proceeding.

Storage and Transport

For storage of the system when not in use, disconnect the power cord and store it in the cart. Remove all loose objects from the top surface. Fold the display down flat. Store the handpiece within the system. Store the laptop in the bag and secure in a safe location. Wipe down the surfaces with a soft cloth. Lock the casters to keep it in place.

The system is provided with the means to easily move it between patients while it is running. To relocate the system while it is running, close just the RetCam Shuttle program, disconnect the power cord , release the front caster locks and gently roll the system to the new location. If the floor is uneven or tiled surface, move the system carefully to avoid damage from excessive vibration. The laptop battery will keep the laptop running for a short period of time based on the charge remaining in the laptop battery. To ensure continued power, plug power cord back into system and power source as soon as the system is relocated to the new location. Once in the new position, lock the casters, reconnect the power cord at both ends, restart the RetCam Shuttle program and continue with imaging.

Hardware Components

- **Notebook Computer:** Pre-loaded with RetCam Shuttle system software, it comes as part of the system. Offers a large LCD display for real-time video and still imaging, image processing and data transfer. A Pentium-based system running Windows® XP Professional, it includes a DVD/R/RW drive, integrated network adapter and USB ports.

Note: For information on the rechargeable battery of the notebook computer, please follow the laptop manufacturer's recommendations located at the following webpage URL; http://usa.twinhead.com/PRO/N15RI

- **Handpiece:** Contains the 3-chip CCD camera. Lightweight and easy to position, it has a long cable for easy reach. Use with changeable lens pieces.
Note: Always return the handpiece to the holster on the work surface when not imaging. The handpiece cable can be draped over the transport handle, but do not wrap it tightly or damage to the fiber optic may result.

- **Handpiece Interconnect Harness:** Contains three separate cables: the lamp (fiber optic) cable for subject illumination, the camera controller cable, and the focus motor cable.

- **Electro-Optical (EO) Box:** Contains the CCD camera control unit, a halogen illumination lamp, and the control circuitry for light intensity, camera focus, image capture and system logic. The front panel has outlets for computer power (DC/DC power) and USB video, the footswitch and the three interconnect camera handpiece harness cables.

- **Tri-Function Footswitch:** A rocker pedal on each side, and a push button in the middle.

    - **Focus control—left pedal**: Rock to the left to focus closer, to the right to focus more distant.

    - **Light intensity—right pedal:** Rock to the left to decrease intensity, to the right to increase intensity.

    - **Snap switch—central push button:** Press to capture and store the current still image, or in video mode, to start and stop recording.

- **Storage Compartment(s):** Particularly useful for safe transport, compartments inside the upper cart door provide storage for the handpiece, the lens pieces, and a container for tools and supplies. Inside the lower door on the right is a compartment for the footswitch.

- **Transport Handle:** Extends to tilt and roll the cart to another location.

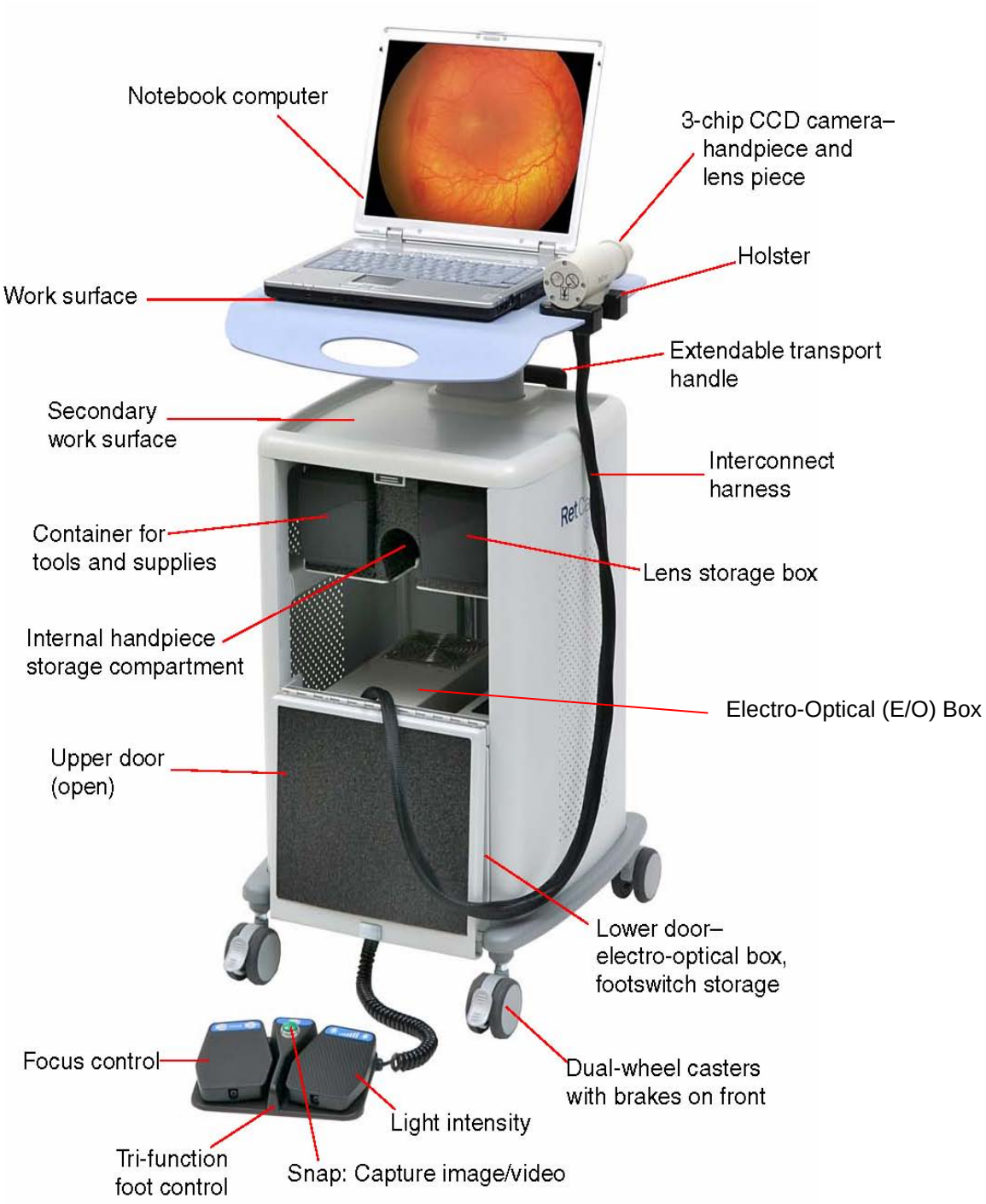


Figure 1. RetCam Shuttle Imaging System

*Image representative only

The Electro-Optical Box

Figure 2. E/O Box
*Image representative only

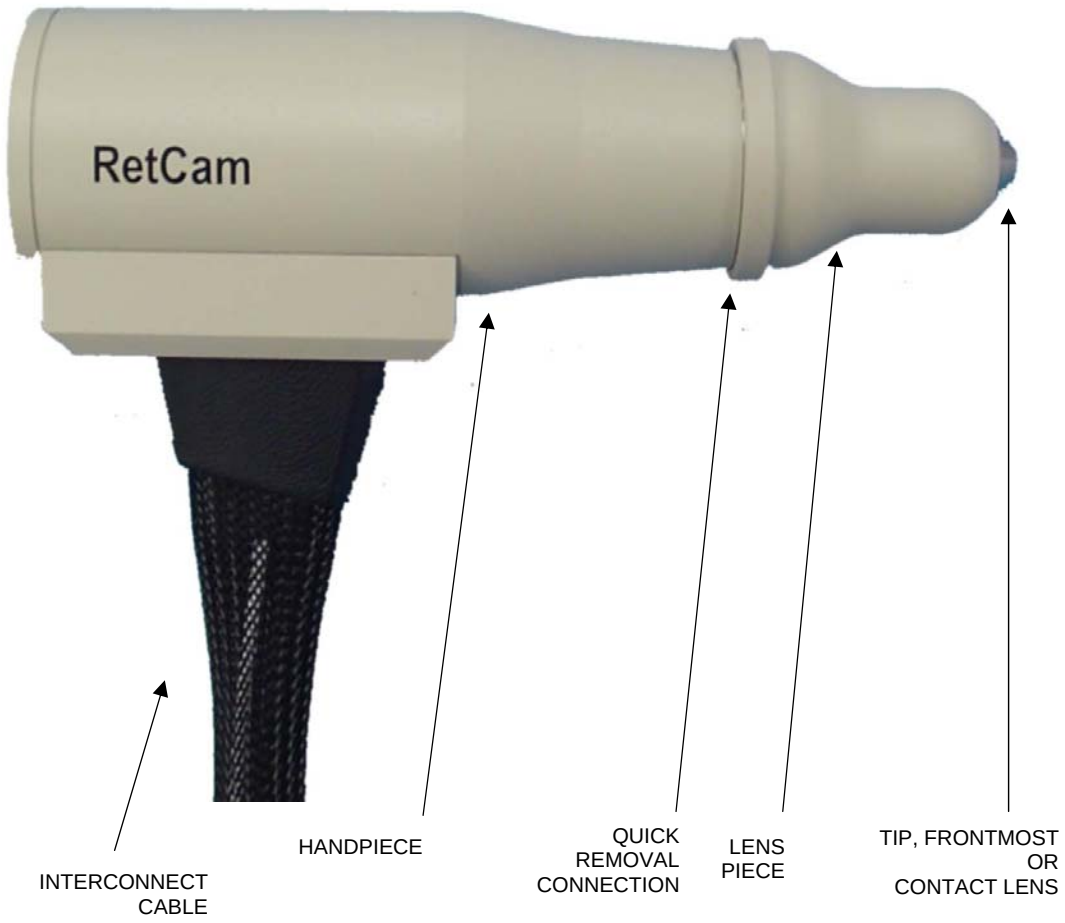


Figure 3. Handpiece and Lens Piece

Figure 4. Lens Piece Selection

Lens Model	Application	Common Field of View
D1300	ROP & Anterior Segment	130 Degrees
E800	High contrast & Posterior	80 Degrees
C300	High Magnification	30 Degrees
PL100	Portrait Lens	N/A

3.0 Maintenance

This section addresses maintenance under the following topics:

3.1 Recommended Maintenance Schedule
3.2 Cleaning Procedures

3.1 Recommended Maintenance Schedule

Between patients: Clean and inspect lens piece.

Weekly: Wipe down the system.

Monthly: Inspect cables and connections for wear.

Burned out bulb: Replace illumination bulb

Blown fuse: Replace system fuses

3.2 Cleaning Procedures

For cleaning purposes, the RetCam Shuttle is divided into two categories:

1. The Lens Piece that contacts the patient
2. The rest of the system

1. Cleaning the Lens Piece

The Lens Piece should be cleaned thoroughly between patients to prevent the spread of infectious disease. As recommended by the American Academy of Ophthalmology, the cleaning liquid of choice is 70% isopropyl alcohol. Moisten a clean towelette with the solution and use a gentle wiping action across the front of the lens piece, being sure to pay special attention to the concave contact lens area. To prevent irritation to the next patient from residue left on the lens, rinse the tip of the lens piece thoroughly with disinfected distilled water.

WARNING: To avoid damage, do not autoclave any part of the RetCam system.

The American Academy of Ophthalmology also recommends disinfecting with 1:10 dilution of bleach for 5 minutes. Refer to the AAO Information Statement, insert in the RetCam Shuttle,
Users Manual. (AAO Information Statement, Recommendations, I., Procedures for Protection of the Patient., Recommendations; D. Disinfection procedures.)

WARNING: To handle chemicals safely, consult Material Safety Data Sheets

(MSDS) before using isopropyl alcohol or bleach.

Note: If you disinfect with bleach, you must rinse the front most part of the lens piece with disinfected distilled water, and make sure the lens piece is wiped completely clean before using on a patient.

Note: Never immerse the entire lens piece or handpiece in any liquid or solution. For disinfection purposes, you can immerse no more than 4 mm (about 1/6”) of the tip of the lens piece, in an inverted position, FOR NO MORE THAN 15 MINUTES. Immersing more or longer than this causes corrosion of the lens piece and voids the lens warranty. Use water, bleach, 3% hydrogen peroxide or isopropyl alcohol. Permissible immersion depth is illustrated in Figure 5 below. It is important not to immerse the joint where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

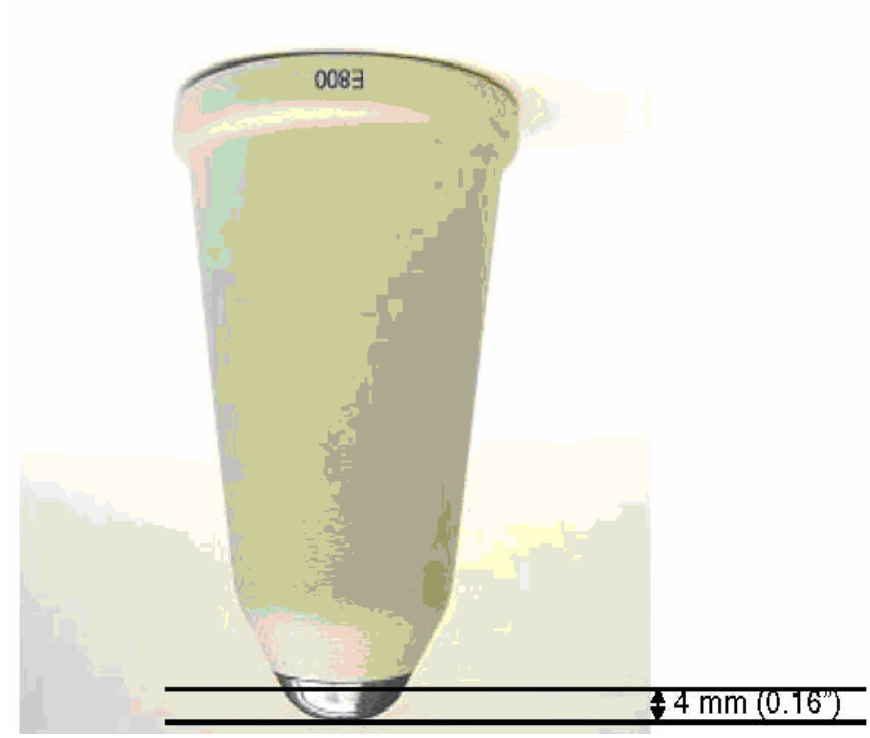


Figure 5. Inverted lens piece showing permissible depth of immersion.

Immersion to only 4 mm

2. Cleaning the Rest of the System

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions directly on the computer or other modules, spray the cloth instead. The cart and side panels also cannot be sprayed, but only the cloth with which you wipe, to avoid introducing spray or mist inside the system. Use only a mild soap and/or water solution.

When cleaning the laptop computer, unplug the computer from the power outlet before cleaning. Use a damp cloth for cleaning. Do not use aerosols, solvents, or strong detergents.

The lens piece should be checked before each use for damage to the front contact lens and surrounding surface. The interconnect cable and connectors should be checked for damage to the end connectors and protective covers.

WARNING: Always inspect the lens before use for damage such as chips, cracks or roughness that could injure the patient’s eye.

4.0 Specifications

Physical

- 19” (483 mm) wide x 19”(483 mm) deep x 34”(864 mm) high
- 75 mm front swivel casters with brakes
- 75 mm rear casters
- Approximately 65 lbs. (30 Kg)
- Low center of gravity
- Temperature range: 59º F to 95º F or 15º C to 35º C
- Humidity range: non-condensing 10% to 95%

Electrical

- Power consumption: 250 VA maximum
- Input Power: 100-240V~, 50/60 Hz
- Detachable hospital grade power cord

Cart Features

- Two storage containers for lenses and supplies
- Internal handpiece holster
- Secondary work surface
- Tri-function footswitch
- Dual 5" front locking casters
- Extendable handle for system transport.

Custom Light Source

- Adjustable intensity iris
- Automatic black and white balance functions
- Lemo focus motor connector
- Custom fiber optic
- Automatic fan speed controller
- Easy-access bulb replacement

Handheld Imager

- 3-chip RGB CCD
- Full 24-bit color
- 30 frames-per-second full-resolution capture
- Quick-change front lens piece, 4 options

Notebook Computer

- Intel® Pentium® M 2.1 GHz processor
- 1GB Random Access Memory
- 80 GB hard drive
- DVD/R/RW drive
- 3 USB connections
- Audio
- 10/100 Ethernet Adapter
- Intel 128MB Video Adapter

Software

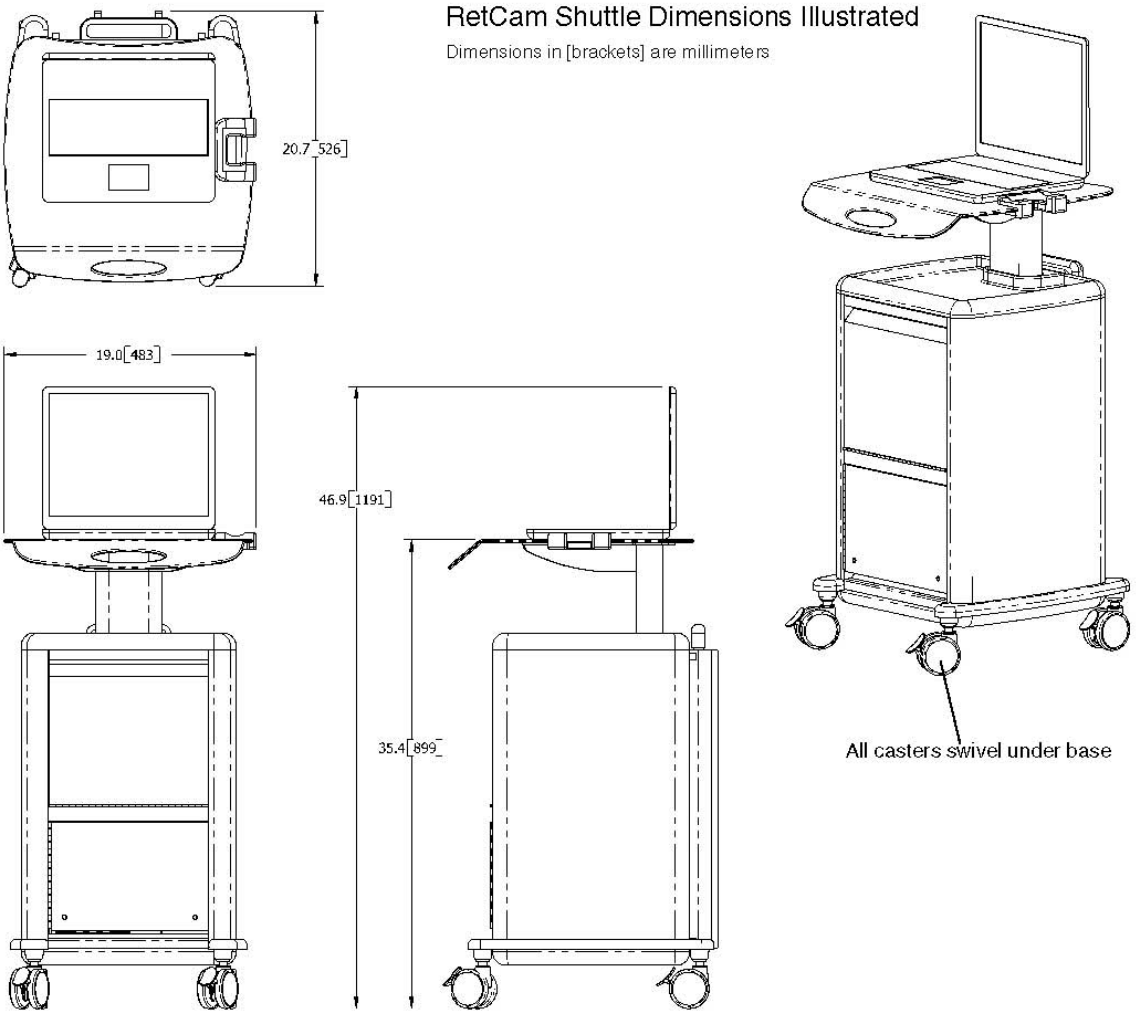
- MS Windows® XP SP2 operating system
- Proprietary image acquisition, storage and processing
- Live color image display
- Integrated patient database
- Still and video capture modes
- Review functions
- Compare functions
- Transfer / backup functions
- Data export as XML, CSV, or TXT with automatic patient organization
- Image export as bitmap, jpeg, or png
- Image annotation

Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures, upright, on a level surface, with the brakes applied to the front casters.

Condition	Operating	Storage and Transport
Temperature	59º to 95º F (15º to 35º C)	-4º to 122º F (-20º to 50º C)
Relative Humidity	10% to 95% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

Note: Specifications subject to change without notice.


RetCam Shuttle Dimensions Illustrated
Dimensions in [brackets] are millimeters
20.7 [526]
19.0 [483]
46.9 [1191]
35.4 [899]
All casters swivel under base

5.0 Service Information

5.1 Troubleshooting Guide

Problem	Troubleshooting steps
No power to laptop.	Check connections. Is the power cord plugged into the back of the system? If not plug the power cord in. Is the main power switch in the back turned on? If not then turn the main power on. Is the laptop power plugged into the laptop and the system? If not, plug cable in.
No Light from handpiece.	Verify the fiber optic from the handpiece is inserted in the fiber optic port of the E/O box. Verify the power switch in the back of the system and on the front of the E/O box are turned on. Turn the power switch off for 10 minutes and then turn it on. This will allow the lamp to cool. If after these measures are taken the lamp does not turn on, then replace the illumination bulb. (Ref section 5.2)
No Live Image.	Check connections Is the USB cable from E/O box to the laptop connected? Verify they are properly plugged in. Is the camera cable securely connected to the E/O box? Verify the camera cable is inserted and threaded on.
Unable to snap image from footswitch.	Close and restart the RetCam Shuttle program.
Images do not transfer.	Verify the Export path and subfolder match the intended destination.
There is no network connection.	Contact your Information Technology (IT) department.

5.2 Changing the illumination bulb

The illumination light bulb located in the E/O Box will need periodic replacement. It is a 12 volt, 75 watt halogen bulb, industry type EKE. Replacement bulbs are available from Customer Service; part number 02-04-501.

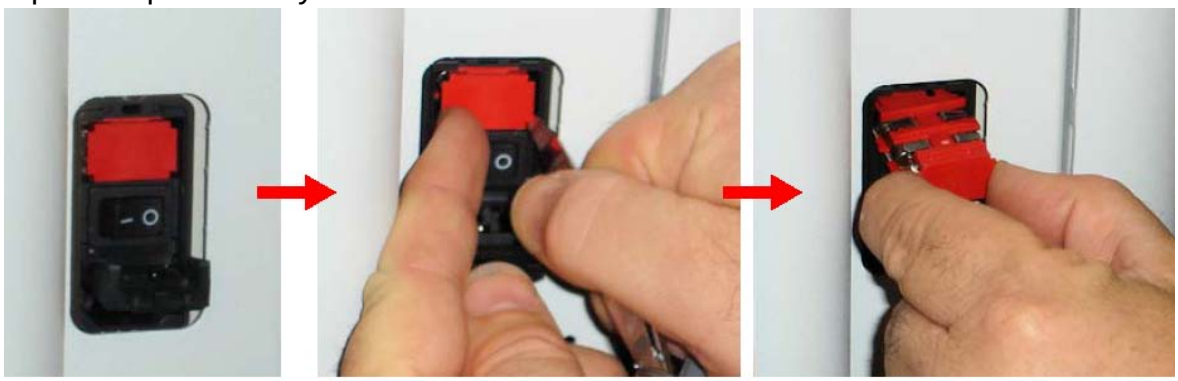
1) Shutdown the RetCam Shuttle according to the user manual, if it is not already turned off.
2) Disconnect the main power cord from the wall.
3) Unplug the fiber optical cable from the front of the E/O Box.
4) Remove the two screws from the small front panel.
5) Grip the handle on the small panel. Pull the small front panel out slowly from the E/O Box. Stop when the light bulb is fully exposed.
6) Remove the illumination bulb from the socket and replace it with the new one.
7) Check the position of the new bulb to make sure that the reflector of the bulb is located in the center of the lamp socket's opening.
8) Push the small front panel back into the E/O Box slowly. Use caution to avoid pinching wires in the area.
9) Replace the two screws on the small front panel.

CAUTION: Do not touch the bulb located in the center of the reflector, or the concave surface of the reflector. Skin oils will adhere to the outside of the bulb, reducing the cooling efficiency of the bulb, creating a hot-spot and subsequent premature burnout. Handle by the reflector only.

5.3 Fuse Replacement

Locate the power entry module on the lower right side of the rear of the cart. Make sure to remove the power cord before proceeding any further.

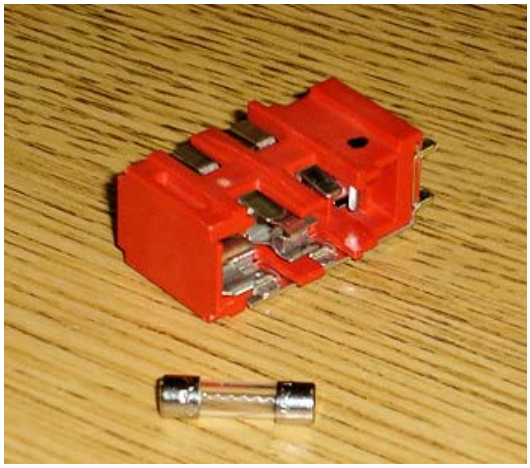
Using a flat blade screwdriver, gently pry open the cover of the fuse holder at the top of the power entry module.



Cover open | Gently pry at edges to start removal | Finish removal with fingers

With the cover open, gently pry at edges to start removal. Finish removal with fingers. Remove the blown fuse from the fuse holder and replace it with a new fuse of same type and rating.

Fuse Type: T 3A / 250VAC slo-blow 5 x 20mm



CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

When you have replaced the blown fuse, reinsert the fuse holder fully and close the cover.

5.4 Servicing the Cart

CAUTION: Removing the back panel should be done by qualified technical personnel only. Maintenance personnel should be familiar with the usual precautions regarding the service of electronic and electrical equipment.

The Laptop, E/O Box, Handpiece and Footswitch are modules that can be removed from the cart for replacement under the direction of the technical service department. Make note of the cable connections before removing a module.

Contact Technical Service for help troubleshooting problems to the module level before attempting repairs.

5.5 Replacement Parts

Spare parts and supplies can be ordered by the following ways from
Customer Service at; 1-800-215-6005
FAX; 1-925-463-7993
or email; service@retcam.com

Consumables:

Illumination Bulb (halogen)	02-04-501
Fuses 3-amp 250 VAC 5x20mm (slo-blo)	20-000097
USB drive, SanDisk	03-12-025
User Manual	20-000106

Components:

Laptop	20-000067
Footswitch	20-000009
Hand-piece	01-00-201
E/O Box	20-000008
Portrait Lens (PL100)	01-00-017
ROP Lens (D1300)	01-00-015
80º Lens (E800)	01-00-016
High Magnification (C300)	01-00-014-1

5.6 Laptop Information

Note: The battery is not fully charged. Allow your battery to fully charge before using it (i.e., before disconnecting AC power). Calibrating the battery before use is also highly recommended. For information on the rechargeable battery of the notebook computer, please follow the laptop manufacturer's recommendations located at the following webpage URL; http://usa.twinhead.com/PRO/N15RI

6.0 Technical Support

6.1 How to Get Support

The User Manual and Service Manual have been written to answer the majority of questions that arise with the product. Please consult these manuals before calling for service.

Clarity Medical Systems, Inc.'s (CMS) in-house technical staff is dedicated to helping our users with any specific problems and questions you may have with the RetCam Shuttle. Please have your serial number ready and include the serial number on all correspondence. The serial number is located on a label affixed to the back of the cart.

Please be as specific and give as much information as possible. If you encounter a system malfunction of any kind, please record the exact steps taken leading to the failure, so that our staff can replicate the problem.

Off-shore customers, please contact your distributor.

In the US, please call: Telephone Support: (800) 215-6005
FAX Support: (925) 251-0078

or write to: Clarity Medical Systems, Inc.
5775 West Las Positas Blvd.
Pleasanton, CA 94588
USA

or email to: service@retcam.com

6.2 Returning Parts for Repair

If a part or component is defective or damaged and is to be returned to Clarity Medical Systems for repair or replacement a Return Materials Authorization Number (RMA #) must be issued by CMS. The RMA number must be noted on the return shipping documents so that the disposition of the part is known when it is received at CMS offices.

Should your CMS product prove defective during the period covered by this warranty, please call, FAX or write to CMS at the numbers and address listed above for an RMA number. Each separate part must be securely packaged and returned to CMS in its original shipping container or an equivalent. Please clearly mark the outside of each returned package with the RMA number.

CMS will, at its option, repair or replace any defective or damaged part or component. Determination regarding whether service and repairs are completed at the customer site or the defective or damaged part(s) are returned to CMS‘s facilities for repair shall be made by CMS on a case by case basis. Costs incurred to complete service or repair, including parts, labor, travel and shipping, not covered by warranty will be billed to the customer upon successful completion of the service or repair.

7.0 Appendix

7.1 RetCam Shuttle Software End User License Agreement

You have acquired a RetCam Shuttle (“DEVICE”) that includes software licensed by Clarity Medical System, Inc. (“CMS, Inc.”) from Microsoft Licensing Inc. or its affiliates (“MS”). Those installed software products of MS origin, as well as associated media, printed materials, and “online” or electronic documentation (“SOFTWARE”) are protected by international intellectual property laws and treaties. The SOFTWARE is licensed, not sold. All rights reserved.

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